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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,640	03/01/2004	Michael D. West	60141.0022USU2	9766
28120	7590	11/17/2008	EXAMINER	
ROPES & GRAY LLP			BERTOGlio, VALARIE E	
PATENT DOCKETING 39/41			ART UNIT	PAPER NUMBER
ONE INTERNATIONAL PLACE				
BOSTON, MA 02110-2624			1632	
MAIL DATE		DELIVERY MODE		
11/17/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/790,640	<b>Applicant(s)</b> WEST ET AL.
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1,3-8,10-67,69-78,80-92 and 94-105 is/are pending in the application.  
 4a) Of the above claim(s) 40-67 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3-8,10-39,69-78,80-92 and 94-105 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's reply dated 10/04/2007, 03/03/2008 and 07/30/2008 have been received. Claims 1,3-5,7,8,10,13,14,21,22,24,25,27,29,32,33,78,82,92,94,95, and 97 have been amended in the response dated 03/03/2008. Claims 2,9,68,79 and 93 have been cancelled. Claims 40-67 are withdrawn. Claims 1,3-8,10-67,69-78,80-92 and 94-105 are pending and claims 1,3-8,10-39,69-78,80-92,94-105 are under consideration in the instant office action.

The instant application is a continuation of USSN 09/527,026, now abandoned.

***Specification***

Applicant's amendments to the specification are noted.

***Double Patenting***

The provisional rejection of claim 1 under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 11/079,930 is withdrawn.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,808,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims in the '704 patent are of a broader scope than the instant pending claims. Further, allowed claims 1 and 4-6 recite the steps of pending claim 1, and with regard to a primary cell, claim 6 is drawn to isolating a fibroblast which is a primary cell. Applicant has remarked that this rejection will be addressed upon indication of otherwise allowable subject matter in this application.

Claims 1,3-8,10-24,29-36, as amended, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 87-92,94-117 of copending Application No. 11/079,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims of '930 are not specifically drawn to mammals, the instant claimed methods utilizing reprogramming of somatic cell nuclei by nuclear transfer were notably used in mammalian species. Thus, the generic claimed "cell" in '930 renders obvious the instant claimed mammalian cell..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-39, and 68-105 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full breadth of the claims is withdrawn in light of Applicant's amendments to the claims.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-8,10-28,30-33 and 69-71, 82-84, and 94-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 remains unclear in the recitation of a 'rejuvenating a primary cell' because the method as claimed does not result in modifying the cell per se, rather results in a different and unique cell. Similarly, claims 21 and 22 comprise a step of rejuvenating a cell.

Applicant has amended the claims to clarify the characteristics of the resulting cell. However, the terminology of the preamble remains the same and remains unclear.

The method as instantly claimed encompasses nuclear transfer techniques wherein the nucleus of the first cell is transferred into a second recipient cell. Once the genetic material is removed from the first cell it is no longer a cell, nor when it is transferred to the recipient cell is it the same cell, rather it is a chimeric cell. Further, in the formation of a teratoma, it is recognized in the art that the cells often do not maintain the proper ploidy or the properties of terminally differentiated cell. While it is not contested that following the instantly claimed method steps the artisan could obtain a cell which resembles cell type of the initial primary cell, however it is unclear if this represents a rejuvenated form of the initial cell. Further, a common property of many primary cells is terminal differentiation wherein the cell no longer

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proliferates. For example, in view of claim 2, it is unclear if the rejuvenated primary cell would also be terminally differentiated, and if unable to proliferate, or near senescence, would it still be considered rejuvenated? Though the method steps are straightforward and clear, the metes and bounds of what a rejuvenated primary cell is, and whether practicing the steps results in said rejuvenated cell is unclear. Claims 2-7,17,18 and 69 depend from claim 1. Claims 23 and 24 depend from claim 21.Claim 70 depends from claim 22.

The aspect of the rejection relating to claims 3,32,33 and 94 as being unclear because it is not known what the source of the control teratoma is, is withdrawn in light of Applicant's amendments to the claims.

The rejection of claim 4 as being unclear because it depends from itself is withdrawn in light of Applicant's amendment to the claim.

Claims 7,14, 82 and 95 remain vague and unclear because the nature of the alteration of the genome is not adequately described. While the claims are amended to recite that the primary cell includes at least one alteration to its genome, this amendment fails to clarify the alteration. There is no baseline for determining the alteration. Applicant has clarified that the alteration is in the cell prior to transfer into a recipient oocyte. However, the claim fails to recite what this alteration is with respect to such that one can determine what is encompassed by the "at least one alteration". For example, the alteration could be that resulting from DNA methylation, changes in DNA conformation, insertions, deletions, mismatches occurring during replication or transgenic insertion or deletion of DNA. Dependent claims 17-20 are included in this rejection because they fail to clarify the basis of the rejection. Claims 17 and 18 depend from claim 7. Claim 83 depends from claim 82. Claim 96 depends from claim 95.

The aspect of the rejection relating to claim 8 as being confusing because the antecedent basis of the second control teratoma in the final step is unclear is withdrawn.

Claim 13 remains unclear in the recitation of “for transplantation into a patient in need of a transplant” because it is unclear if this is an intended use for the tissue or a limitation wherein the tissue generated must be capable of being transplanted. It remains unclear whether the tissue must be capable of transplantation or if the phrase is merely reciting an *intended* use. If the latter is the case, the phrase has no patentable weight.

Claim 25 remains confusing and unclear because an animal with the same genotype cannot be genetically different so cannot be altered. From the recited method steps it is unclear how the animal is genetically altered. It is not clear what standard the term “altered” is in comparison to. Claims 26 and 28 depend from claim 25.

The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn.

Claim 84 remains unclear because the metes and bound of the terminology “substantially the same” is unclear. Applicant argues that the offending term has been cancelled. However, claim 84 has not been amended.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent.

- 1) The rejection of claims 1,3-8,10-20,22-24,29-36 under 35 U.S.C. 102(a) and (c) as being

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anticipated by Strelchenko et al. (US Patent 6,011,197) or Damiani et al. (US Patent 6,258,998) as evidenced by Evans et al. (Nature Genetics 23:90-93) is withdrawn.

Claims 21,25-28,37-39,69-78,80-92 and 94-105 remain rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Strelchenko et al. (US Patent 6,011,197) or Damiani et al. (US Patent 6,258,998).

The teachings of Evans are no longer applicable to the claims.

However, claims 21,69-78,80-92 and 94-105 are product by process claims drawn to cells, embryos and tissues made using a nuclear transfer process. Such cloning products do not differ from any other standard cloning protocols that may differ in method steps from the claimed processes. Claims 25-26 are drawn to recloning methods to result in a cloned animal wherein the donor cell has been genetically modified. Claim 37 merely requires transfer of a nucleus into a recipient oocyte.

Strelchenko et al. teach a method of nuclear transfer wherein the resulting cell is used in methods to clone a bovine. Damiani et al. teach a method of nuclear transfer wherein the resulting cell is used in methods to clone an ovine. Further, Strelchenko et al. and Damiani et al. each teach that the methodology can be used to generate an animal in which a heterologous sequence is introduced. In addition, though The specification relies on the methods taught in the art for the practice of the claimed invention, and since practicing the methods inherently transferred mitochondria, the methods of Strelchenko et al. and Damiani et al. anticipate the claims.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (In re Ludke). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain, and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA i977) citing In re Brown, 59 CCPA 1036, 459

F.2d 531, 173 USPQ 685 (1972). In the instant case, it is unclear how the instantly claimed methods and the resulting cells from said methods are materially different from the methods of nuclear transfer known and taught in the art. Thus, the products made by the methods taught in Strelchenko et al. and Damiani et al. each anticipate the instantly claimed products.

2)The rejection of claims 1,3-8,10-20,22-24,29-36 under 35 U.S.C. 102(b) as being anticipated by Robl et al. (WO 98/07841) as evidenced by Evans et al. (Nature Genetics 23:90-93, 1999) is withdrawn.

However, claims 21,25-28,37-39,69-78,80-92 and 94-105 remain rejected under 35 U.S.C. 102(b) as being anticipated by Robl et al. (WO 98/07841) as evidenced by Evans et al. (Nature Genetics 23:90-93, 1999).

The limitations of the claims are summarized above.

Robl et al. taught a method of cross-species nuclear transfer wherein the resulting cell is a chimeric cell comprising an enucleated oocyte which is different from that of the transferred nuclei. Robl et al. do not specifically teach that they transfer any specific amount of mitochondria, however at the time of the claimed invention it was recognized that in performing nuclear transfer techniques that enucleation and the transfer of nuclei resulted in the exchange of mitochondria as evidenced by Evans et al. As noted above, where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products, *hi re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531,173 USPQ 685 (1972). In the instant case, it is unclear how the instantly claimed methods and

the resulting cells from said methods are materially different from the methods of nuclear transfer known and taught in the art. Thus, the methods taught in Robl et al. anticipate the instantly claimed methods and products produced by said method or other claimed methods not covered by the instant rejection.

Applicant's arguments have been fully considered and are persuasive as they relate to the majority of the method claims. However, the rejection is maintained over the product by process claims as the product fails to differ from that made by processes known in the art. The remaining rejected method claims fail to differ from the cloning methodology known in the art. Claim 25, for example uses known methodology and relies on a starting material that is a product by process, that fails to differ from products known in the art.

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/  
Primary Examiner  
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